

PATENT/Docket No. 6231.N CN1
Appl. No. 09/500,246
Filing Date: February 8, 2000
Reply to Office action of January 15, 2005

REMARKS

I. Preliminary Remarks and Amendments

Claims 26-28, 32-38, and 42-50 are currently under consideration and stand rejected. Claims 26 and 36 are amended herein. Claims 34-35 are cancelled. Claims 51-52 are new claims. Support for the additions and amendments to the claims is found throughout the specification and the original claims. Accordingly, the additions and amendments do not include new matter.

Applicants do not intend by any amendments or cancellations to abandon the subject matter of any claim previously presented. Applicants reserve the right to pursue the subject matter of such claims in duly filed continuing applications, and any issues of patentability will be addressed at that time. This response is timely filed with an Extension of Time.

II. Patentability Arguments

Reconsideration and withdrawal of the objections and rejections is solicited for the reasons set out below.

A. The Objection to Claim 27 under 37 CFR §1.75(c) May be Properly Withdrawn.

Claim 27 was objected to under 37 CFR §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 26 was amended to recite a mixture of tablets and pellets, and thus Claim 27 is not broader in scope than Claim 26. Claim 36 was also amended in this manner. The support for this amendment to Claims 26 and 36 is found in the specification on page 6, line 28, through page 7, line 22. Support is also found in original Claims 2-3 of the Application as filed, which are now cancelled. Applicants respectfully request reconsideration and withdrawal of the objection under 37 USC §1.75(c).

B. The Rejection of Claims 26-28, 32-33, 36-38, 42-50 under 35 USC §112, Second Paragraph, May Properly Be Withdrawn.

In the Office Action, Claims 26-28, 32-33, 36-38, and 42-50 were rejected under 35 USC §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention." Examiner states that "there is no indication in the Specification as to what would be considered a large particle size. The term 'large' is a relative term which renders the claim indefinite. The term 'large' is not defined by the

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claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. If Applicant means that the particle size in the second delivery vehicle is larger than the particle size in the first delivery vehicle then the claim should clearly indicate the same." The Applicants respectfully traverse this rejection.

Applicants have amended Claims 26 and 36, as shown above. Claims 27-28, 32-33, 48, and 50 depend from Claim 26; Claims 37-38, 42-47, and 49 depend from Claim 36. In addition, Applicants have added new Claims 51 and 52, which depend from Claims 26 and 36, respectively.

Support for the changes to Claims 26 and 36 is found in the specification, particularly on page 7, lines 6-22, and page 8, line 30 through page 9, line 5, and in Example 1.

Support for Claims 51 and 52 can be found in the Specification on page 2, lines 28-32, where Applicants state, "Release of drugs from pellet or tablet based implants is driven primarily by the solubility of the drug in the plasma or fluids at the implantation site and the effective surface area of the dosage form. The rate is determined by the solubility and effective surface area while the duration of release is a function of the amount of drug load in the pellets." Further, on page 6, lines 28-34, of the application, Applicants state, "Examples of **immediate-release vehicles** include, but are not limited to the following: coated solids of liquids where the coating wall material is very thin, coated solids or liquids where the coating wall material is very soluble in body fluids, porous or freeze-dried solids having an increased surface area contact, a solid tablet or pellet containing a disintegrating agent which causes the solid tablet to rapidly break down when in body fluids, a solid or pellet containing a relatively small or micronized active particle size, an osmotic delivery system where the osmotic system is such that a substantial amount of active is released upon implantation, and mixtures thereof." Then on page 7 lines 6-11 of the Specification Applicants state, "The **second delivery vehicle** comprises a sustained release delivery system. As practical matter, the skilled artisan may select any of the following non-limiting sustained release delivery vehicles to contain the actives of the implant of the claimed invention: encapsulated solutions or suspensions, biodegradable solid substances, **conventional tablet/pellet formulations optionally utilizing either disintegrating agents and/or**

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active particle size to modulate release, conventional tablet/pellet formulations coated with....."

Independent claims 26 and 36 are not indefinite for the reasons stated herein. Claims 27-28, 32-33, 37-38, 42-52 which depend from Claims 26 and 36, are also not indefinite because they depend from claims that are not indefinite.

For the foregoing reasons, the Applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph.

C. The Obviousness Rejection of Claims 34 and 35 under 35 USC §103(a) May Be Properly Withdrawn.


Claims 34-35 were rejected under 35 USC §103(a) as, assertedly, "being unpatentable over Cady et al. (US Pat. 6,498,153) in view of Okada et al. (US Pat. 4,652,441), Babcock et al. (US Pat. 3,417,182), Montgomery et al., and Grimm (US Pat. 5,522,797)."

Applicants have canceled claims 34-35. Thus, the rejection of these claims under 35 USC §103(a) is rendered moot. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §103(a). Applicants reserve the right to pursue the subject matter of these claims in a duly filed continuing application, and any issues of patentability will be addressed at that time.

III. Conclusions.

In view of the amendments and remarks made herein, Applicants respectfully submit that Claims 26-28, 32-33, 36-38, and 42-52 are in condition for allowance and respectfully request expedited notification of same.

Respectfully submitted,


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Date: July 19, 2005

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